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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
09/830,761	06/18/2001	Rolando Barbucci	1756	2132	
75	7590 05/14/2004		EXAM	EXAMINER	
Walter H Schneider 21530 Beechwood Road			WHITE, EVERETT NMN		
Circleville, OH			ART UNIT	PAPER NUMBER	
			1623		
		DATE MAILED: 05/14/2004			

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)				
	09/830,761	BARBUCCI ET AL.				
Office Action Summary	Examiner	Art Unit				
	EVERETT WHITE	1623				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply - If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	36(a). In no event, however, may a reply be within the statutory minimum of thirty (30) will apply and will expire SIX (6) MONTHS from the application to become ABANDO	e timely filed days will be considered timely. om the mailing date of this communication. NED (35 U.S.C. § 133).				
Status						
 Responsive to communication(s) filed on <u>21 January 2004</u>. This action is FINAL. 2b) This action is non-final. Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i>, 1935 C.D. 11, 453 O.G. 213. 						
Disposition of Claims						
 4) ☐ Claim(s) 12,15,18 and 19 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) 12,15,18 and 19 is/are rejected. 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) are subject to restriction and/or election requirement. 						
Application Papers						
9) The specification is objected to by the Examine 10) The drawing(s) filed on is/are: a) access applicant may not request that any objection to the Replacement drawing sheet(s) including the correct 11) The oath or declaration is objected to by the Examine	epted or b) objected to by th drawing(s) be held in abeyance. § ion is required if the drawing(s) is	See 37 CFR 1.85(a). objected to. See 37 CFR 1.121(d).				
Priority under 35 U.S.C. § 119						
 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) ☒ All b) ☐ Some * c) ☐ None of: 1. ☐ Certified copies of the priority documents have been received. 2. ☐ Certified copies of the priority documents have been received in Application No 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 						
Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date	4) Interview Summa Paper No(s)/Mail 5) Notice of Informa 6) Other:					

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DETAILED ACTION

1. The amendment filed December 18, 2003 and supplemental amendment filed January 21, 2004 has been received, entered and carefully considered. The amendment affects the instant application accordingly:

- (A) New Claim 19 has been added;
- (B) Claims 1-11, 13, 14, 16 and 17 have been canceled;
- (C) Claims 12 and 18 have been amended;
- (D) Comments regarding Office Action have been provided drawn to:
 - (a) 102(b) rejection, which has been maintained; &
 - (b) 102(e) rejection, which has been maintained.
- 2. Claims 12, 15, 18 and 19 are pending in the case.
- 3. The text of those sections of title 35, U. S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

- 4. Claims 15, 18 and 19 stand rejected under 35 U.S.C. 102(b) as being anticipated by Pouyani et al (US Patent No. 5,616,568) for the reasons already of record in the previously filed Office Actions.
- 5. Claims 15, 18 and 19 stand rejected under 35 U.S.C. 102(e) as being anticipated by Prestwich et al (US Patent No. 5,874,417) for the reasons already of record in the previously filed Office Actions.

Claim Rejections - 35 USC § 103

6. Claims 12, 15, 18 and 19 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Prestwich et al (US Patent No. 5,874,417) in view of Galin et al (US Patent No. 5,944,753) for the reasons already of record in the previously filled Office Actions.

Arguments

7. Applicant's arguments filed December 18, 2003 have been fully considered but they are not persuasive. Applicants amended Claim 18 by inserting language, which set forth "cross-linkage occurs only through amino bonds between carboxy groups of the

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hyaluronic acid and the amino groups of a diamine" and argues that the language overcomes the rejection of the claims. The language inserted into the claims is acceptable, however, the rejections of the claims over the references of record are maintained since the references used to reject the claims set forth cross-linked hyaluronic acid, which is carried out by reacting the carboxy group of hyaluronic acid with the amino groups of a dihydrazide compound. The diamine compound of the instant claims encompasses the dihydrazide compound set forth in the references when the A symbol in the diamine formula "NH2-A-NH2" disclosed in Claim 18 is a C2-C6 chain which may be substituted with carboxy and other amino groups as set forth in the instant specification and instant Claim 19. For example, see Scheme 1 in column 4 of the Pouvani et al patent and column 7 of the Prestwich et al patent wherein hyaluronic acid is reacted with a dihydrazide, which embraces the instantly claimed diamine when A in the formula in instant Claim 18 is represented as a C₂-C₆ chain and substituted with carboxy and amino groups as set forth in instant Claim 19. The dihydrazido-HA compound in the references is used to produce crosslinked hyaluronic acid compounds. Accordingly, the rejection of the claims under 35 U.S.C. 102 as being anticipated by the Pouyani et al and Prestwich et al patents and the rejection of the claims under 35 U.S.C. 103 as being unpatentable over the Prestwich et al patent in view of the Galin et al patent is maintained for the reasons of record.

8. The rejection of the claims under 35 U.S.C. 103 as being unpatentable over the Prestwich et al patent in view of the Galin et la patent was intended as a new ground of rejection over the claims, which was needed to reject the subject matter of instant Claim 12. It should have been made clearer that the withdawal of the 103 rejection in the last Office Action was in reference to the previously filed 103 rejection presented prior to the last Office action.

Summary

9. All the pending claims are rejected.

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Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Examiner's Telephone Number, Fax Number, and Other Information

11. For 24 hour access to patent application information 7 days per week, or for filing applications, please visit out website at www.uspto.gov and click on the button "Patent Electronic Business Center" for more information.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Everett White whose telephone number is (571) 272-0660. The examiner can normally be reached on Monday-Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reach on (571) 272-0661. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

≨m∖es O. Wilson

Supervisory Primary Examiner

Technology Center 1600